

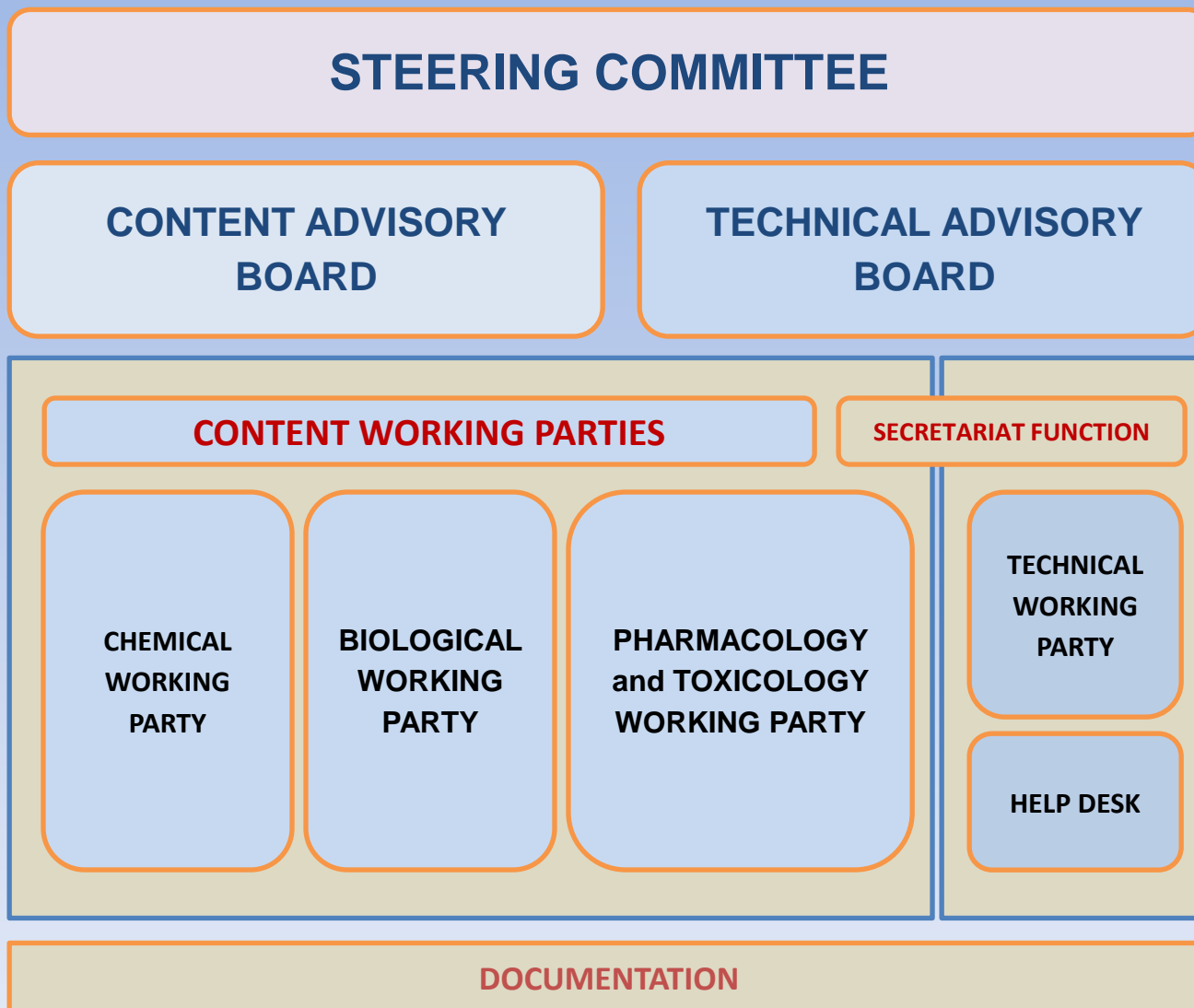


# Organization of GInAS

GInAS Summer Meeting, 13.09.2013

Session 2

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# Stakeholders

- Regulatory Bodies
- Innovative and Generic Industry (MAH)
- Manufacturers
- Health Care Professionals
- Health Research Organizations
- Universities

# User Access Classification

- Guest:
  - No registration needed
  - Public domain access only!
- Organizations:
  - Roles and permissions depend on organization
  - Individual User registered/validated by organization
  - Each user is classified regarding his/her role
- **Registered users can get additional permissions**

# System Access

- **Only registered systems can have access to interfaces or services:**  
GInAS provides access to data via technical interfaces like restful services or web services
- Systems can only be registered as by organizations
- Systems have guest access plus individual permissions
- Interfaces are for two way communication

# Roles

- Guest
- User or System
- Editor
- Reviewer
- Secretariat
- Content Administration (Meta Data)
- User Administration
- System Administration
- Help Desk

# Permissions

Role	Create	Read	Update	Delete	Review	Release	Process	Admin	User Admin
<b>Guest</b>		X							
<b>User or System</b>		X							
<b>Editor</b>	X	X	X	X					
<b>Reviewer</b>		X			X				
<b>Secretariat</b>		X	X	X		X	X		
<b>Content Administration</b>		X	X					X	
<b>User Administration</b>									X
<b>System Administration</b>	X	X	X	X		X		X	X
<b>Help Desk</b>		X					X		

# Public Domain Data

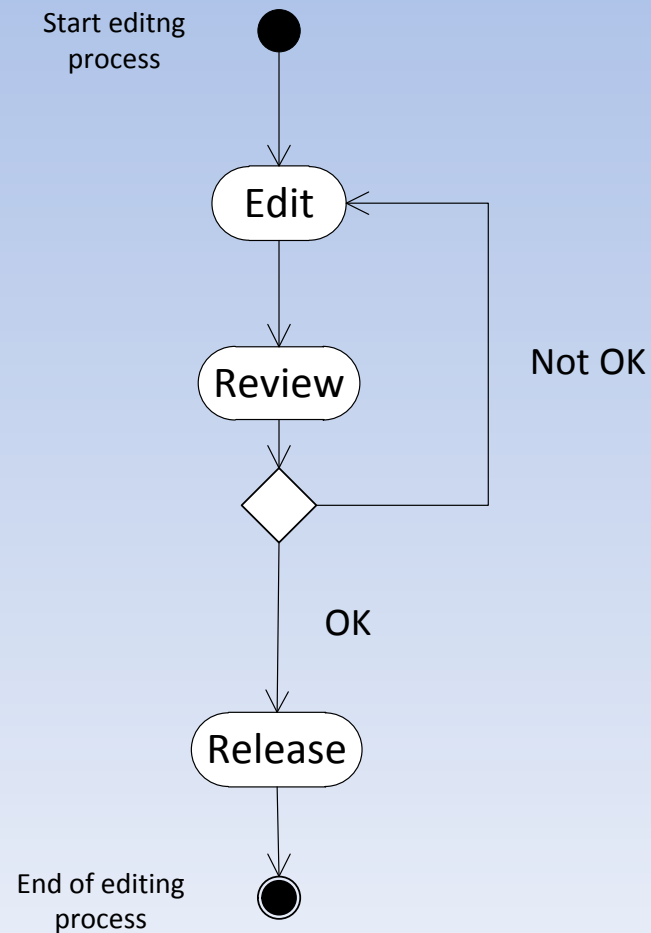
- Data published by a reliable source (e.g. WHO, Pharmacopeia, Scientific Journals ...)
- **Providing an unique substance identifier**
- If not marked as confidential:  
Names, Codes,  
Specified Substance (Level 1),  
Structures or Descriptions,  
Molecular Weight, Molecular Formula
- Source References



# Confidential Data

- Confidential Data can be:
  - Public Data marked as confidential
  - Data from Dossiers or Application Form
  - Data from Clinical Trials or other Studies
  - Internal Company Data
  - Reviews and Remarks from Regulators

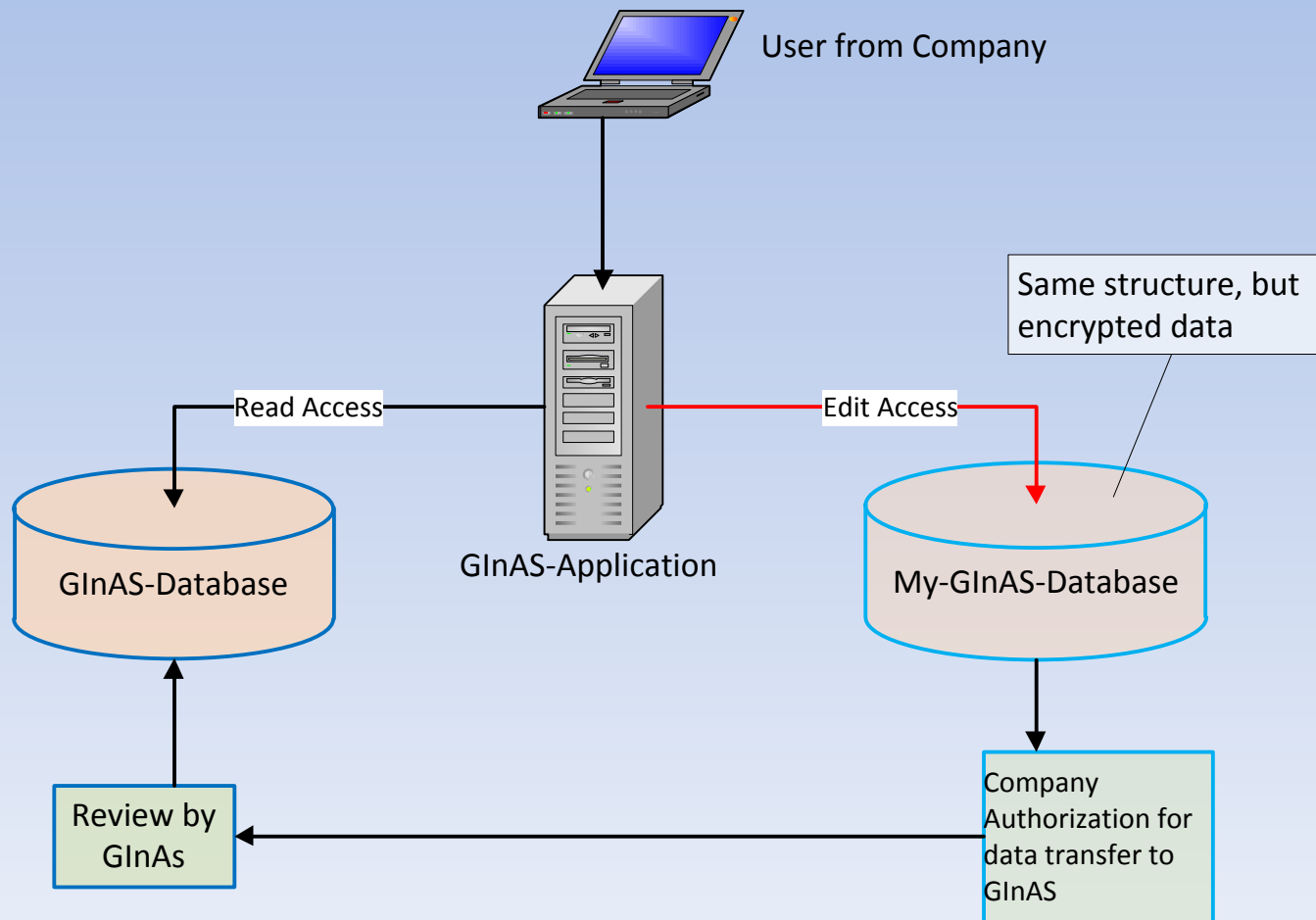
# Edit and Review Process of a Substance



# Company Specific Data Entry to GInAS

- Companies are allowed to enter own data to the quarantine area “My-GInAS”
- Data will be stored **encrypted** in a second instance of database
- Only the company has access to these data
- Data transfer to GInAS can be authorized by **the company only!**
- After review data will be imported into GInAS

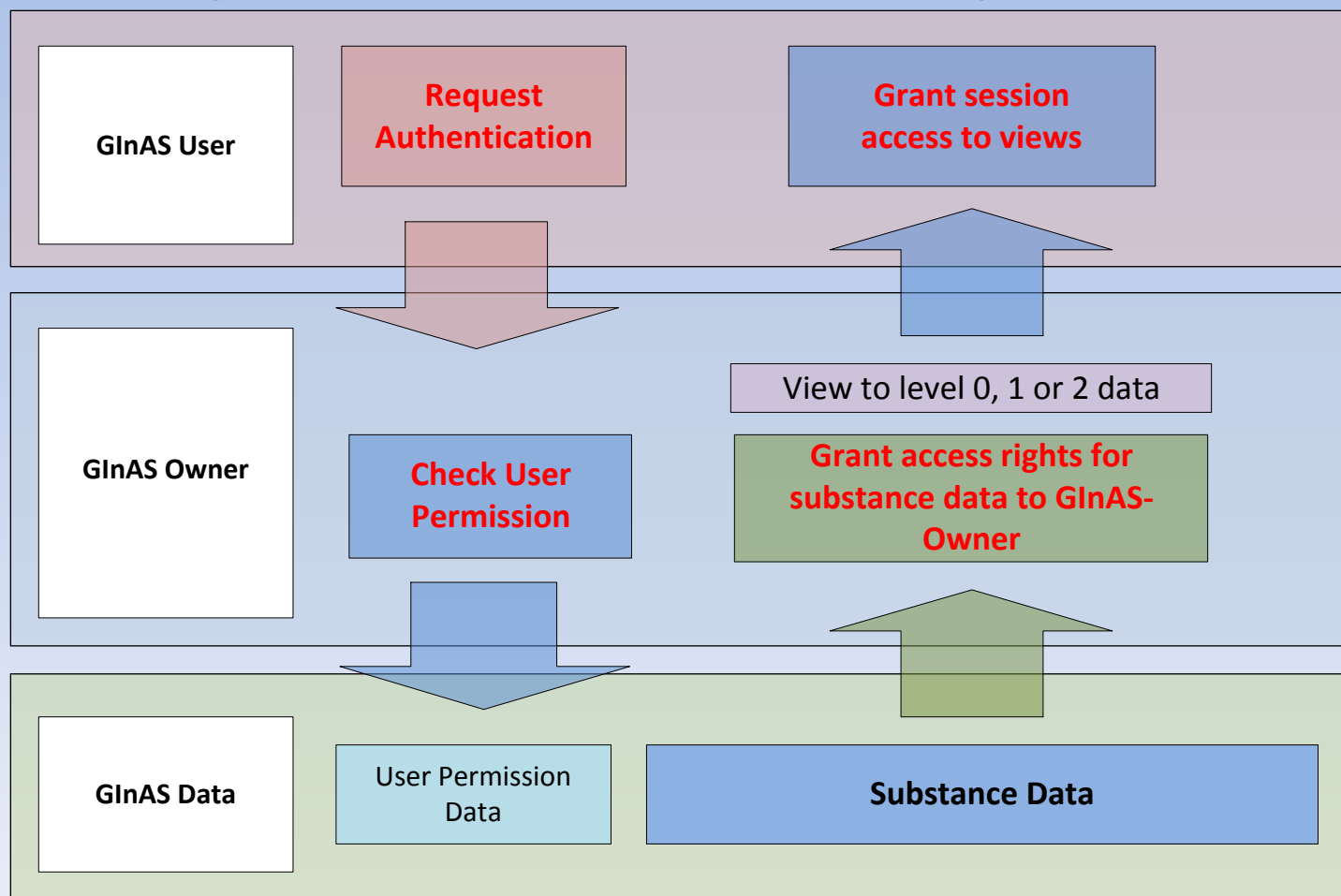
# My-GInAS



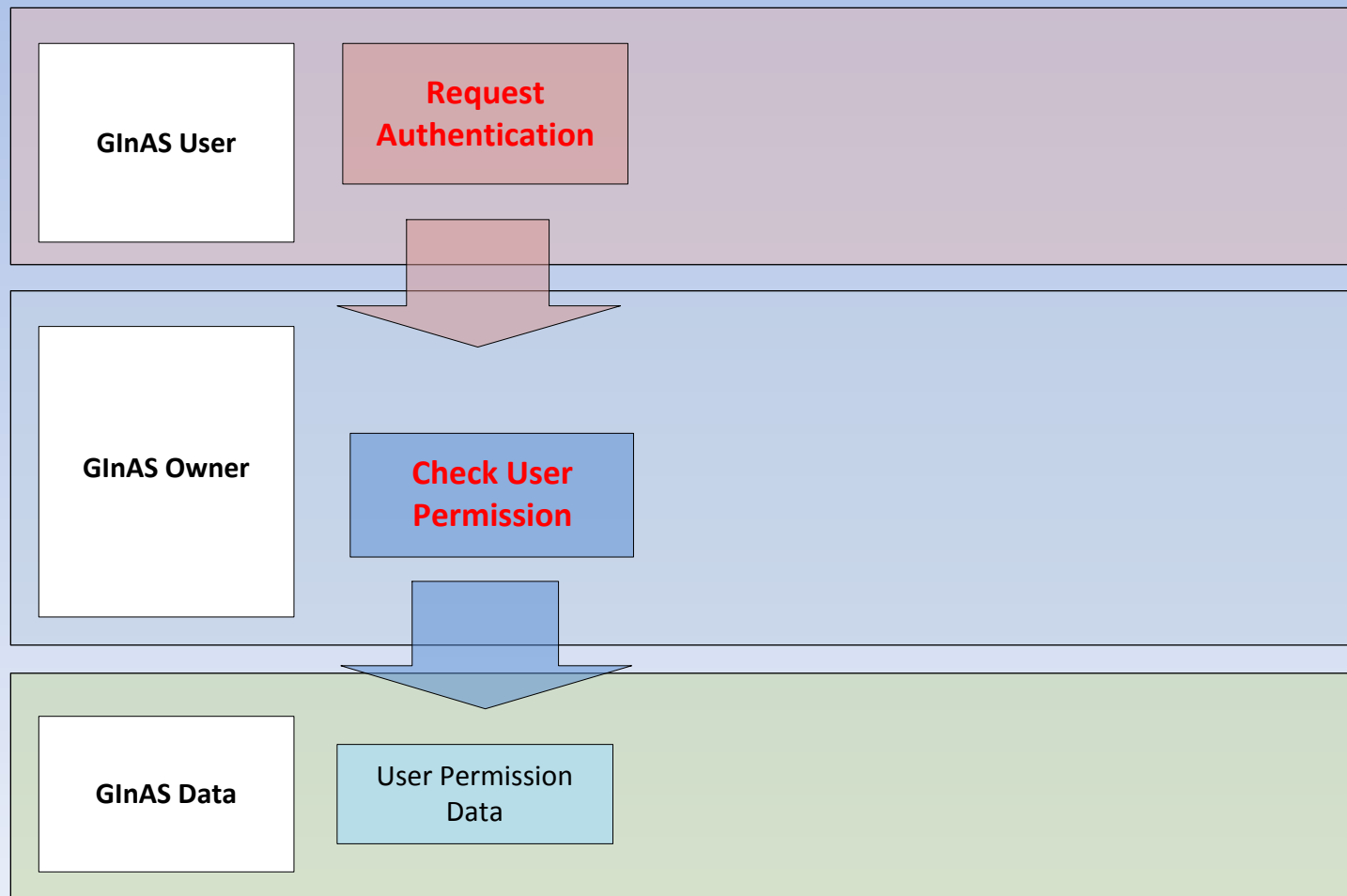
# Data Levels of Security

- Physical Levels of security:
  - GInAS-User account
  - GInAS-Owner account
  - GInAS-Data account

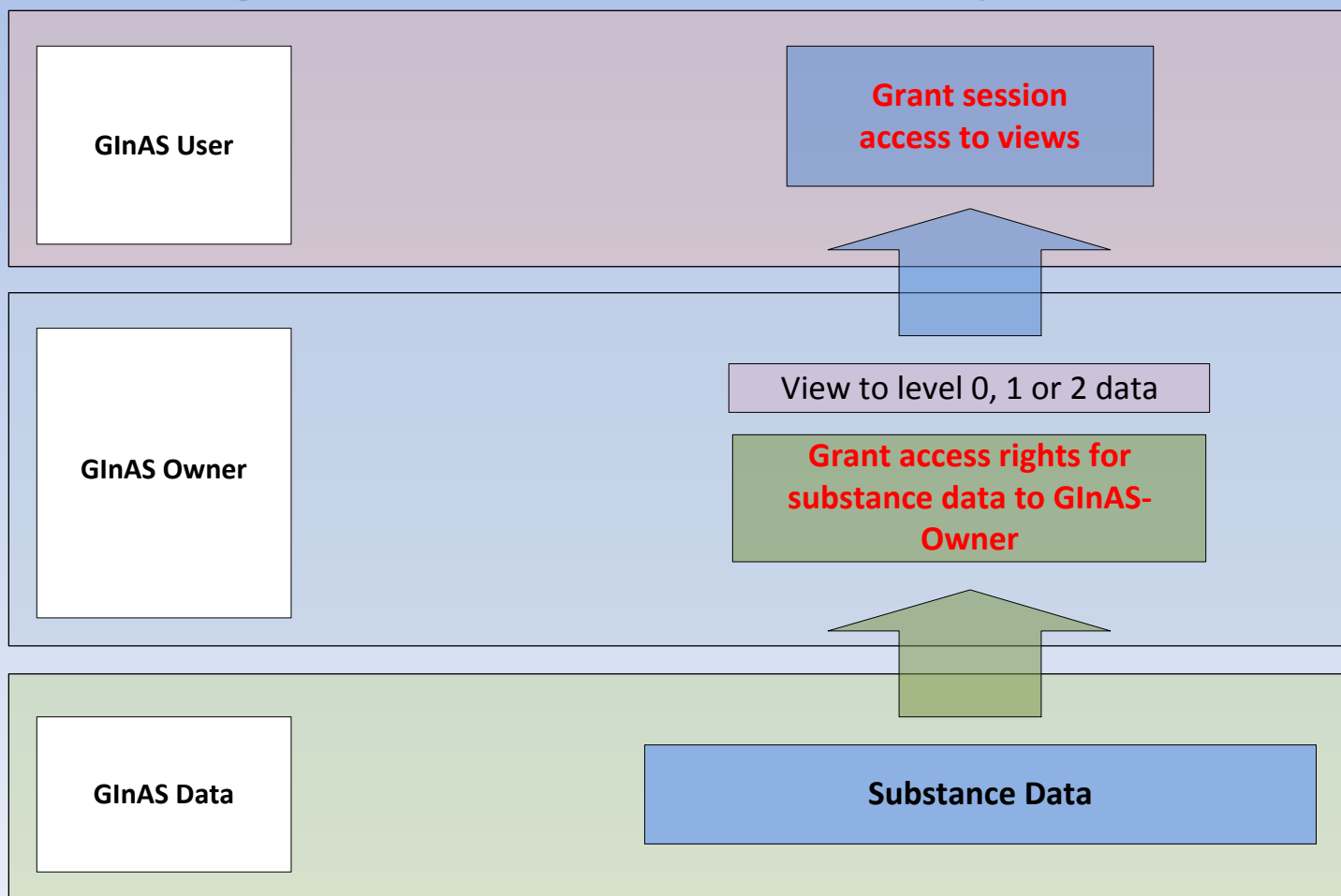
# Security Access Schema per Session



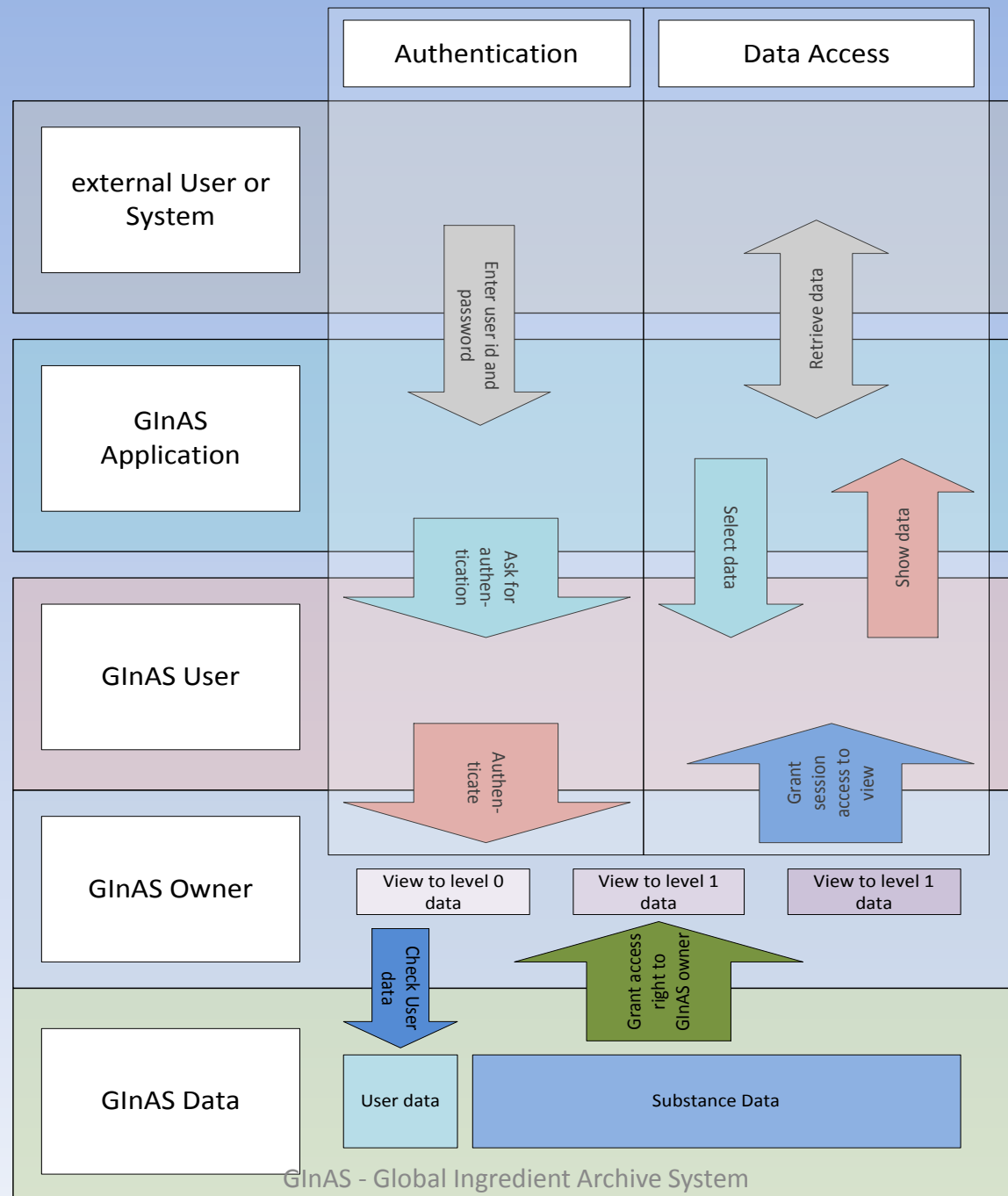
# Authentication Process per Session



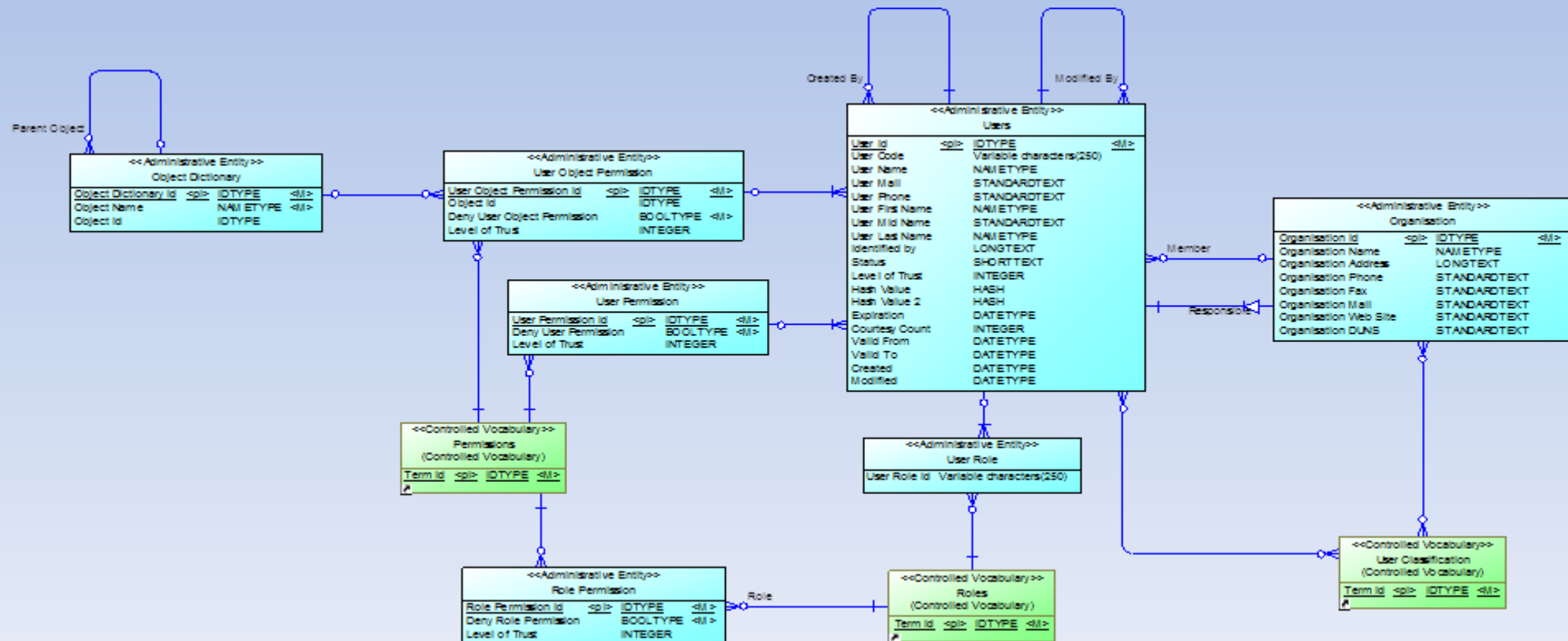
# Granting Access to Data per Session







# Conceptual Data Model for Users, Roles and Permissions



# Thank you for listening!

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